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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,348	07/03/2003	Gary Sederholm	IOI-454	7308

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,348	Applicant(s) SEDERHOLM ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/20/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Objections

2. Claim 9 is objected to because of the following informalities: please add --the-- in front of "stem" (see line 6).. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Regarding claim 14, "the neck taper" (see line 1) lacks antecedent basis.
- b. Regarding claim 15, "the proximal body taper" (see line 1) lacks antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3738

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 5-10, and 13-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Markus et al. (EP 1 059 070; cited in Applicants' IDS).

Referring to Figure 2, Markus et al. disclose a modular hip implant comprising a stem (1) extending from a proximal end to a distal end; a neck (3) being rotationally adjustable (capable of being adjusted) about the stem; a proximal body (2) being rotationally and axially adjustable (capable of being adjusted) about the stem, and having a threaded section (17); an expansible collet (clamping sleeve 15 and/or "thin-walled case" 9) positionable (capable of being positioned) between the stem and proximal body; and a locking member (8) having threads *adapted to engage* (emphasis added to functional language) the threaded section to lock the proximal body and collet together and to the stem.

7. Claims 9, 13, and 15-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Powell (US 5,906,644).

Referring to Figures 1-33, Powell discloses a modular hip implant comprising a stem (e.g., 12; 212; 312) extending from a proximal region to a distal region; a neck (e.g., 20; 320) being rotationally adjustable (capable of being adjusted) about the stem; a proximal body (e.g., 24; 324) being both rotationally and axially adjustable (capable of being adjusted) about the stem; a flexible sleeve (e.g., 32'; 332) lockingly engageable (capable of being engaged) between the stem and proximal body; and a locking member (e.g., 34; 336) *adapted to engage* (emphasis

added to functional language) the proximal body and lock the proximal body to the stem. The sleeve includes a plurality of longitudinal slots (e.g., 33; 333).

8. Claims 1, 5-10, and 13-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Doubler et al. (US 6,692,530 B2).

Referring to Figures 1 and 4-6, Doubler et al. disclose a modular hip implant comprising a stem (11) extending from a proximal end to a distal end; a neck (46/41 and 16 collectively) being rotationally adjustable (capable of being adjusted) about the stem; a proximal body (20) being rotationally and axially adjustable (capable of being adjusted) about the stem, and having a threaded section (threads 51); an expansible collet (40) positionable (capable of being positioned) between the stem and proximal body; and a locking member (13) having threads *adapted to engage* (emphasis added to functional language) the threaded section to lock the proximal body and collet together and to the stem. Said locking member has a ring shape in cross-section.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2-4, 11, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markus et al. (EP 1 059 070; cited in Applicants' IDS) in view of O'Neil et al. (US 5,755,800 A).

Markus et al. disclose the invention as claimed (see 102(b) rejection above). Although Markus et al. disclose an interlocking system involving a proximal portion having internal threads, they did not particularly disclose their locking member as a cylindrical nut with external threads. However, this is already known in the art. For example, O'Neil et al. disclose a modular joint prosthesis (Figure 5: character 80) comprising a stem (peg 22); a proximal portion (augmentation block 84) having internal threads 108; a split sleeve/collet (compression collet 88) having longitudinal slots; and a locking member (securement device 90). Securement device 90 is a cylindrical nut with external threads 120 (see column 7, lines 14-25). The arrangement of this interlocking system involves placing compression collet 88 between peg 22 and augmentation block 84. Once in this position, securement device 90 is engaged with augmentation block 84 by threading external threads 120 of securement device 90 onto internal threads 108 of augmentation block 84 (see column 6, line 46 to column 7, line 67), and compressing the compression collet 88 in order to create and maintain a secure engagement between the components of the modular joint prosthesis (see column 7, line 65 to column 8, line 7). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an interlocking system for a modular joint prosthesis comprising a locking member having the shape of a cylindrical nut with external threads, as taught by O'Neil et al., with the interlocking system of the modular joint prosthesis of Markus et al., in order to create and maintain a secure engagement between the components of the modular joint prosthesis.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: White (US 6,428,578 B2), Rogers et al. (US 6,663,670 B2), Gerbec et al. (US 6,875,239 B2), Daniels et al. (US 2004/0122525 A1), and Monfardini et al. (EP 0 634 154 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

June 23, 2005



David H. Willse
Primary Examiner